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Applicant: Dr. h. c. Robert Mathys Stiftung et al.

Amendment under Article 19 PCT

1. In the enclosure a set of amended claims 1 to 33 is filed replacing all claims presently on file.

2. Amendments have only be carried out in claim 1, in which it has now been clarified that the fibers (2) on top of the base component (4)

   form a brush-like structure.

3. Document D1 teaches a fiber-reinforced, polymeric implant material useful for tissue engineering. The fibers thereby are always embedded in a porous or non-porous material.

   According to page 7, lines 8 to 13, such an implant material can be used as one phase of a multiphase implant as e.g. described in US 5,607,474 (D5). Also D5 shows porous polymeric materials only, in which according to D1 (WO 98/53768) fibers can be embedded.

   Therefore, it is a first difference between the present invention and document D1 that the fibers according to the present invention are not embedded in any other material, which is clearly expressed by the language "brush-like structure" in newly filed claim 1.

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Furtheron, D1 generally teaches that the fibers can be predominantly oriented in a single direction or in a single plane. However, from the process described on page 14, lines 19 to 28 there is no indication of the orientation of the predominant alignment of the fibers in one direction.

There seems to be no particular need for choosing a defined orientation of the predominant alignment as the fibers are embedded in a matrix material anyway. Therefore, in contrast to the present invention, the contour of the top layer of a multiphase implant according to D1 (when combined with D5) is defined by the matrix material and not by the fibers.

To summarize, the second substantial difference between the present invention and D1 is that, although D1 suggests that the fibers can be aligned in one direction, there is no teaching that this alignment has to be parallel to the insertion axis of the prosthetic device.

4. The brush-like structure is mentioned literally for example on page 6, line 23 and page 12, line 25 of the present invention.

   The advantage of the brush-like structure, in combination with a provision of a stabilization area, as well described on page 5, last paragraph to page 6, first paragraph. The brush-like arrangement of the fibers according to the present invention provides for a particularly advantageous basis for the ingrowth of articular chondrocytes resulting in a rapid cartilage growth, thus assuring a long term cartilage replacement.

5. Examples 1 and 2 describe a process for anchoring the fiber layer into the base component, which actually consists in a grafting of the fiber layer (as a distinct entity) to the anchoring base component. In contrast to the manufacturing process described in D1, the manufacturing process as described for example in examples 1 and 2 of the present invention can achieve a fiber layer having a brush-like structure.

6. As the fibers according to D1 are embedded in a polymeric matrix anyway, there is no need to provide for a stabilization area as proposed by the present invention. The stabilization area according to the present invention is necessary to anchor the aligned fibers in a brush-like structure to the base component (4).

7. It is true that document US 2001/0039455 A1 (D2) teaches a multi-layer composite structure formed from several layers of different materials. The first layer (54) is made from biostable polycarbonate polyurethane. An intermediate, central layer is made from polycarbonate polyurethane 55-D and the third layer is made from polycarbonate polyurethane 80-A or a

thermoplastic hydrogel coating. Again, D2 teaches a "composite structure" only, but no fibers material.

It has already been explained above that due to the matrix structure proposed by D1, there is no need in such a structure (in contrast to the brush-like structure according to the present invention) to provide for a stabilization area.

On the other hand, D2 cannot give any suggestion as how to anchor brush-like arranged fibers, as it is completely silent about fibers as such.

8. Note that also EP 1 277 450 A2 (D3) teaches a composite scaffold being made of porous material only, but not having any fibers layer.

9. None of the prior art documents shows a brush-like alignment of fibers on top of a base component. Consequently all of the prior art documents fail to teach a stabilization area for anchoring the layer comprising the fibers in the base component.

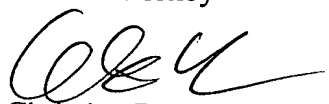
   The present invention is against the trend of embedding fibers in a matrix material according to D1 and for the first time teaches the provision of a distinct fiber-only layer on top of a base component.

   The subject-matter of new claim 1 (as well as of all depending claims) therefore is neither anticipated nor rendered obvious by the prior art documents on file.

   It is therefore kindly requested to issue an International Preliminary Examination Report (IPER) acknowledging the patentability of claim 1 and the depending claims.

   As a matter of precaution a (second) opinion is requested before issuing the examination report.

Patent Attorney



Christian Rupp

Enclosure:
set of amended claims 1 to 33

RMS Stiftung

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Amended Claims

1. A prosthetic device for repairing or replacing cartilage or cartilage like-tissue (1) comprising
- at least one layer comprising at least partially oriented fibers (2),
- a base component (4) to anchor said at least one layer of fibers (2) in subchondral environment and
- a stabilization area (3) provided between said at least one layer comprising fibers (2) and said base component (4),
wherein said fibers (2) are aligned essentially in parallel to the insertion axis of the prosthetic device and form a brush-like structure.

2. The device according to claim 1,
wherein said fibers (2) are aligned to more than 50, preferably more than 90 %.

3. The device according to claim 1 or 2,
wherein the fiber material (2) includes a mineral material, synthetic polymers or molecules, natural polymers or molecules, biotechnologically derived polymers

or molecules, biomacromolecules, or any combination thereof.

4. The device according to claim 3, wherein the fiber diameter is in a range of 50 nm to 1 mm.

5. The device according to claim 4, wherein said fiber diameter is in a range of 1 μm to 250 μm.

6. The device according to any of claims 3 to 5, wherein the fibers (2) have a liquid absorbing capacity in a range of 0,1 to 99,9 %.

7. The device according to claim 6, wherein said liquid absorbing capacity is in a range of 20,0 to 99,0 %.

8. The device according to claim 6 or 7, wherein the liquid is an aqueous solution and/or body fluids.

9. The device according to at least one of claims 1 to 8, wherein the base component (4) comprises a material used as a bone substitute.

10. The device according to claim 9,
wherein said bone substitute is a material as defined in claim 3.

11. The device according to claim 9,
wherein said material is a synthetic ceramic containing at least one of the following components: calcium phosphate, calcium sulfate, calium carbonate, or any mixture thereof.

12. The device according to claim 11,
wherein said calciumphosphate containing at least one of the following components: di-calciumphosphatedihydrate ($CaHPO_4x2H_2O$), dicalciumphosphate ($CaHPO_4$), alpha-tricalciumphosphate (alpha-$Ca_3(PO_4)_2$), beta-tricalciumphosphate (beta-$Ca_3(PO_4)_2$), calcium deficient hydroxylapatite ($Ca_9(PO_4)_5(HPO_4)OH$), hydroxylapatite ($Ca_{10}(PO_4)_6OH_2$), carbonated apatite ($Ca_{10}(PO_4)_3(CO3)_3)(OH)_2$), fluorapatite ($Ca_{10}(PO_4)_6(F,OH)_2$), chlorapatite ($Ca_{10}(PO_4)_6(Cl,OH)_2$), whitlockite ($(Ca,Mg)_3(PO_4)_2$), tetracalciumphosphate ($Ca_4(PO_4)_2O$), oxyapatite ($Ca_{10}(PO_4)_6O$), beta-calciumpyrophosphate (beta-$Ca_2(P_2O_7)$), alpha-calciumpyrophosphate, gama-calcium-pyrophosphate, octacalciumphosphate ($Ca_8H_2(PO_4)_6x5H_2O$).

13. The device according to claim 9,
wherein said material is a synthetic ceramic containing

metallic, semimetallic ions, and/or non-metallic ions, preferably magnesium, silicon, sodium, potassium, and/or lithium.

14. The device according to any of the claims 9-11b wherein the material is a composite material comprising at least a polymer component and a mineral phase.

15. The device according to any of claims 9 to 14, wherein the bone substitute material is highly porous with interconnecting pores.

16. The device according to any of claims 9 to 15, wherein the shape of the base component (4) is round cylindrical or conical.

17. The device according to claim 16, wherein the diameter of the base component (4) ranges between 2 and 30 mm, with a height being 1 to 30 mm.

18. The device according to claim 16, wherein the diameter of the base component (4) ranges between 4 and 20 mm, with a preferred height being between 1 to 6 mm.

19. The device according to at least one of claims 1 to 18 wherein said stabilization area (3) is a zone comprising at least one layer.

20. The device according to claim 19, wherein said zone has a thickness of 1 nm to 1 mm.

21. The device according to claim 19 or 20, wherein said zone is porous.

22. The device according to any of claims 19 to 21, wherein the layer system is composed of a chemical substance.

23. The device according to at least one of preceding claims further comprising at least one externally added component.

24. The device according to claim 23, wherein said components are cells of different origin.

25. The device according to claim 24, wherein said cells are autologous cells, allogenous cells, xenogenous cells, transfected cells and/or genetically engineered cells.

26. The device according to claim 23, 24 or 25, wherein chondrocytes, chondral progenitor cells, pluripotent cells, tutipotent cells or combinations thereof are present throughout the fiber layer(s) (2).

27. The device according to claim 23, 24 or 25, wherein osteoplasts, osteo progenitor cells, pluripotent cells, tutipotent cells or combinations thereof are present throughout the base component (4).

28. The device according to claim 23, 24 or 25, wherein blood or any fraction thereof is present throughout the base component (4).

29. The device according to claim 23, wherein pharmaceutical compounds are contained.

30. A prosthetic device for repairing or replacing cartilage or cartilage like-tissue (1) comprising
- at least one layer comprising at least partially oriented fibers (2),
- a base component (4) to anchor said at least one layer of fibers (2) in subchondral environment and
- a stabilization area (3) provided between said at least one layer comprising fibers (2) and said base component (4),

wherein said fibers (2) are aligned essentially perpendicularly to a top surface of the base component facing the fibers.

31. A prosthetic device for repairing or replacing cartilage or cartilage like-tissue (1) comprising
- at least one layer comprising fibers (2),
- a base component (4) to anchor said at least one layer of fibers (2) in subchondral environment and
- a cell barrier layer provided between said at least one layer comprising fibers (2) and said base component (4).

32. A use of the device according to at least one of the preceding claims for implantation in articulating joints in humans and animals.

33. The use according to claim 32 for regeneration of articulator cartilagenous tissue.